Efficacy in Low Level Laser Therapy for Body Contouring and Spot Fat Reduction

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OBJECTIVE:
There were two primary study objectives: (1) To improve body contouring as evidenced by girth measurement reduction of 2 cm along the waistline, and (2) To improve body contour as evidenced by photographs showing a better and more defined body contour.

RESEARCH METHODS:
Forty generally healthy men and women between the ages of 18 and 65 with a body mass index (BMI) of no greater than 29.9 kg/m2 were randomized in a 1:1 ratio to an experimental treatment or to a control treatment. The study took place over an eight (8) week period. Each subject had two treatments per week for a total of eight (8) treatments over 4 weeks. All subjects were instructed not to modify their exercise or diets for the duration of the study.

CONCLUSION:
The LipoLaser gives a significant girth loss that is sustained over repeated treatments and is cumulative over 4 weeks of 8 treatments. This girth loss of approximately one inch from the waist was accompanied by a clinically and statistically significant improvement in appearance.

RESULTS:
Each treatment with the LipoLaser gave an approximate loss of 0.4 cm to 0.5 cm in waist girth. This difference, 0.405 cm (Laser -0.059 +/- 0.708 cm vs. Placebo -0.19 +/- 0.47 cm (mean +/- SD), was significant ($p<0.05$) on the third treatment done during week two. The cumulative girth loss at treatment three was a significant 1.74 cm (Laser -1.895 +/- 2.967 cm vs. Placebo -0.16 +/- 2.458 cm) ($p<0.05$). Cumulative girth loss at 8 weeks of treatment was 2.15 cm (Laser -0.781 +/- 2.817 cm vs. Placebo 1.353 +/- 2.644 cm) in those who maintained their weight within 1.5 kg of their baseline weight ($p<0.05$). The standardized pictures of the participants showed a significant 1.21 (Laser 1.21 +/- 0.419 vs. 0 + 0 cm) difference between the LipoLaser and the placebo treatment in appearance on a 0-3 scale favoring the LipoLaser group when comparing the baseline to the week 8 pictures ($p<0.001$). When only those participants that remained within 1.5 kg of their baseline weight were considered, the improvement in appearance increased to 1.25 (Laser 1.25 +/- 0.447 vs. 0 +/- 0) on a 0-3 scale between the LipoLaser group compared to the placebo group when contrasting the baseline to the week 8 pictures ($p<0.001$).

Summary of Data presented by Mary Kate Caruso at The Obesity Society's 2007 Annual Scientific Meeting, October 20, 2007, New Orleans, LA

Key Words:
Body Mass Index, LASER, Low Level Laser Therapy (LLLT), Region of Interest (ROI), Girth

EXHIBIT
Bissoon 22
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Background

LASER is acronym for Light Amplification by Stimulated Emission of Radiation. Laser based devices are used for a broad array of medical applications. Biological effects of non-thermal laser light have been documented and published for over 30 years. Therapeutic devices are typically used in pain relief and aesthetic medicine. The LipoLaser is a semiconductor based Low Level Laser Therapy (LLLT) device. Meridian originally developed the Lipo Laser system for pain relief - carpal tunnel syndrome. Minor modifications were made to adapt the device to aesthetic application - body contouring and spot fat reduction. Body toning, sculpting and contouring is mostly related to fat reduction but not always treated as part of an obesity program. This device is not intended to treat obesity, but rather so-called trouble spots, or spot fat reduction such as so called "love handles".

LipoLaser Device Description

The Meridian LAPEX 2000 Lipo Laser System is a low level laser therapy device consisting of a main console, 2 multi-probes, and 2 enhancement probes. The console houses the main electronics, controls and embedded software. The LCD displays all key treatment parameters. The main console is also equipped with a micro controller that provides automatic calculation of energy output for a specific set of treatment parameters. Frequency, treatment time and output power are adjustable using a keypad displayed on the LCD menu. The multi probes each contain 4 LEDs that are the laser emission source. These probes are nonthermal and non-invasive.

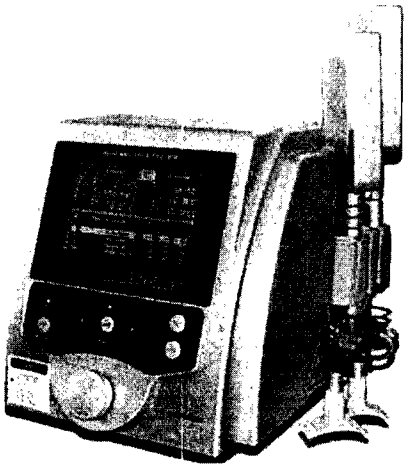


Figure 1. The Meridian LipoLaser is a solid-state, semi-conductor powered Class IIIB laser operating between the 630 and 680 nm wavelengths. Small and portable, it weighs just 13.6 lbs.

Table 1 LipoLaser Demographics

Variable	A	P	P-Value
Number enrolled	20	20	
Gender			0.0765
Female	19	15	
Male	1	5	
Age (Years)	35.1	38.35	0.3292
SD	9.11	11.55	
Weight (kg)	63.97	67.31	0.3705
SD	8.23	14.31	
Height (cm)	164.12	165.68	0.5341
SD	5.99	9.32	
Body Mass Index (kg m^{-2})	23.77	24.35	0.4641
SD	2.02	2.87	
SBP	120.15	121.40	0.7330
SD	11.98	11.00	
DBP	75.35	75.00	0.8922
SD	8.23	8.00	

Values are means and standard deviation (SD)

Mechanism of Action

Low level laser devices have been well documented over the years for their role in biostimulation at the cellular level. While this has been used in pain relief, publications such as Solarte et al, Laser induced lipolysis on adipose cells have well documented the use of laser devices on fat cells. The publication further states that a 635 nm laser alone is capable of releasing triglycerides through the cell membrane. Intra-cellular fat is also released from adipocytes when adipose tissue is irradiated with cold red laser. The LipoLaser uses the multi beam to emit a cold red laser at a wavelength of 635-680 nm that irradiates adipocytes that are present in adipose tissue. The released triglycerides (fat) are eliminated from the body through normal metabolic processes.

Methods

This is a 2-arm, blinded, single center Phase III registration or pivotal trial. Eligible subjects, body mass index < 30.0 kg/m2 were randomized to either an experimental treatment or a placebo treatment. The experimental arm utilized the LipoLaser its normal operating mode, while the control arm utilized the device with the multi-probes inactivated.

Randomization was created from random number tables and the treatment codes were stored in sealed envelopes during the study. The subjects were blinded to the treatment arm. Baseline measurements and photographs were obtained using a standardized protocol. Each subject in the experimental arm had a LipoLaser treatment for 30 minutes, twice a week for 4 weeks. Standardized measurements and photographs were obtained at baseline, study visit 3 and study visit 8, both pre-treatment and post-treatment. The camera position was fixed, and a reference point on the waistline was marked with a marker that lasted for the duration of the study. The waistline measurement was determined per National Institute for Health guidance (NIH) at the iliac crest using a tape measure with standardized tension and parallel to the floor.

Forty subjects were randomized to two treatment arms in a 1:1 ratio giving 20 per subjects per treatment group. Subjects completing at least 4 treatment sessions were included in the analyses.

Inevaluable subjects were included in the Intent-To-Treat (ITT) population. Subjects who voluntarily withdrew from the study were not included in the completer's analysis. Case Report Forms were used to collect data, such as pretreatment measurements, post treatment measurements.

Two individuals conducted the study. One administered the treatment, and the other who was blinded to treatment allocation obtained measurements and photographs. The individual administering the treatment remained blinded to photographic and girth measurements.

During the first treatment, each subject was advised about the rules of blinding, and were told that the individual taking photographs and measurements could not relay this information to the subject. The individual administering the treatment left the room when photographs and when photographs and measurements are obtained. A new Case Report Form (CRF) was used each time measurements were obtained. No reference to or review of the subject's previous CRFs were permissible.

Figure 1

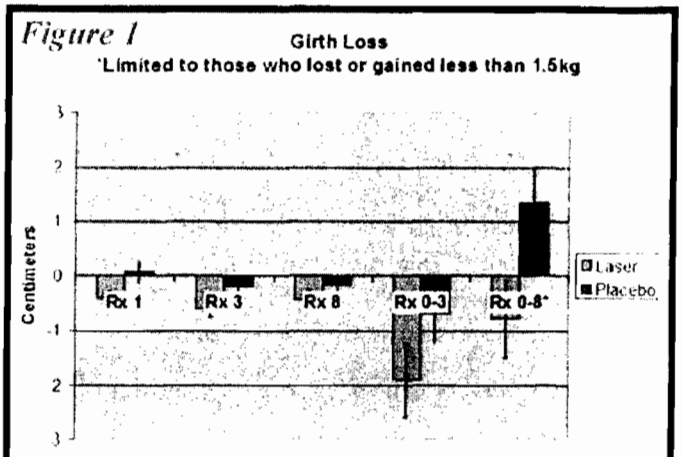


Figure 2

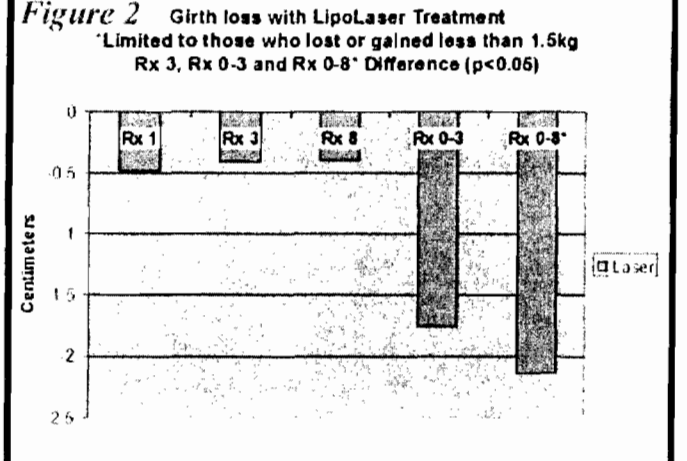
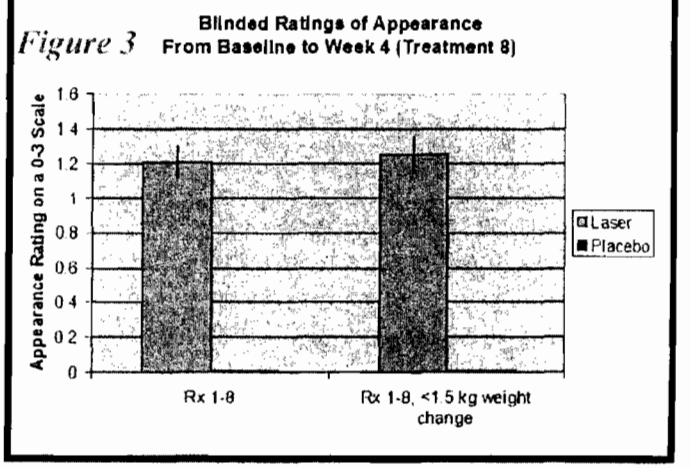


Figure 3



Results

Only one subject who was in the treatment group dropped from the study. This subject, who left due to scheduling conflicts, was in the treatment group and lost 0.2 cm with the initial treatment. The groups were well balanced at baseline and the group characteristics are illustrated in Table 1. Each treatment with the LipoLaser gave an approximate loss of 0.4 cm to 0.5 cm in waist girth. This difference, 0.405 cm (Laser -0.59 +/- 0.708 cm vs Placebo -0.19 +/- 0.47 cm (mean +/- SD), was significant ($p<0.05$) on the third treatment done during week two on the completers analysis, but not by intent to treat.

The cumulative girth loss at week three of treatment twice a week was a significant 1.74 cm (Laser -1.895 +/- 2.967 cm vs. Placebo -0.16 +/- 2.458 cm) ($p<0.05$) on both the completers analysis and by intent to treat. Cumulative girth loss at treatment 8 (4 weeks of treatment) was 2.15 cm (Laser -0.781 +/- 2.817 cm vs. Placebo 1.353 +/- 2.644 cm) in those who maintained their weight within 1.5 kg of their baseline weight ($p<0.05$). The standardized pictures of the participants showed a significant 1.21 difference (Laser 1.21 +/- 0.419 vs. Placebo 0 +/- 0 cm) in appearance on a 0-3 scale favoring the LipoLaser group comparing the baseline to the week 8 pictures ($p<0.001$). When only those participants that remained within 1.5 kg of their baseline weight were considered, the improvement in appearance increased to 1.25 (Laser 1.25 +/- 0.447 vs. Placebo 0 +/- 0) on a 0-3 scale comparing the baseline to the week 8 pictures ($p<0.001$). Girth losses in the laser and placebo groups at the various time points are illustrated in Figure 1.

The girth difference in the Laser group compared to the placebo group is illustrated in Figure 2. The differences in appearance from baseline to week 8 in the whole group and the subjects who remained within 1.5 kg of their baseline weight are illustrated in Figure 3.

Conclusion

A single LipoLaser treatment was shown to be effective in giving girth loss, and repeated treatments remained effective giving approximately a 0.4 to 0.5 cm girth loss per treatment. This difference was statistically significant at week three demonstrating that the effect of the Lipolaser does not appear to diminish with repeated treatments through time. The 1.74 cm girth loss at treatment three suggests that the LipoLaser treatments twice a week are cumulative in their effect on girth loss.

It is obvious that weight change over the course of treatment would change waist circumference and confound the results. The subjects selected for the study were asked not to lose or gain weight over the course of the study. Since some subjects did gain or lose a significant amount of weight over the 4 week study, the cumulative fat loss was analyzed only on those subjects whose weight was within 1.5 kg of their baseline weight. The selection of a 1.5 kg limit for weight fluxuation was based on the fact that this study was the length of a 4-week menstrual cycle minimizing the effect of menstrually-related fluid shifts in women. Girth loss over the course of the study was greater than 2 cm and statistically significant. The subjects in this study were not obese and an approximate 1 inch reduction in waist girth over the course of 8 treatments and 4 weeks was clinically significant. The blinded ratings of the baseline pictures compared to the treatment 8 (week 4) pictures taken in a standardized way demonstrated an improvement in appearance that was highly statistically significant. As expected, the improvement was greater when limiting the comparison to only those subjects that remained within 1.5 kg of their baseline weight. Thus, the LipoLaser gives a significant waist girth loss that is sustained over repeated treatments and is cumulative over 4 weeks of 8 treatments. This waist girth loss was almost one in inch in magnitude and gave both a clinically and statistically significant improvement in appearance.

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